

DELOIS L. SHELTON
OFFICE OF REGULATORY AFFAIRS
WEIDER NUTRITION GROUP, INC.
1960 SOUTH 4250 WEST
SALT LAKE CITY, UTAH 84104-4836
TELEPHONE (801) 975-5031
FACSIMILE (801) 972-4454

4/29/97

April 16, 1997

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James Tanner, PhD
Acting Director, Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
HFS-450
200 C Street SW
Washington DC 20204

Re: *Submission of Structure/Function Claims*

Dear Dr Tanner:

After an audit of our files, we are submitting structure/function claims which may not have been previously filed with your office or may have been reworked with wording changes and substantiation verification. Enclosed are the structure/function claims for the following nutrients, as generated by Dr. Luke Bucci:

- 1) Creatine Monohydrate
- 2) Proton (Protein Hydrolysate)
- 3) Multiple Vitamin/Mineral/Herbal Diet System
- 4) Vitamin A
- 5) Selenium
- 6) Blue Thunder (carbohydrate, proteins, caffeine, proprietary energy blend)
- 7) Beta Carotene
- 8) High Energy (caffeine and ginseng)

975-0162

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We welcome the opportunity to receive feedback from your office as we continue to interpret how to write structure/function claims as allowed by the Dietary Supplement Health and Education Act. There are some areas of overlap between nutrient functions or their effects on body structure and health claims. We anticipate that we will continue to fully comply with your interpretation of health claims.

Please feel free to contact me if you have further questions or comments.

Respectfully,

A handwritten signature in black ink, reading "De Lois L. Shelton". The signature is fluid and cursive, with a long horizontal line extending from the end of the name.

De Lois L. Shelton, Regulatory Compliance

cc: Dave Mastroianni, Luke R. Bucci